IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

NIPPON SHINYAKU CO., LTD., Plaintiff, v. SAREPTA THERAPEUTICS, INC., Defendant.	C.A. No. 21-1015 (GBW) [redacted] [redacted]
SAREPTA THERAPEUTICS, INC. and THE UNIVERSITY OF WESTERN AUSTRALIA, Defendant/Counter-Plaintiffs, v. NIPPON SHINYAKU CO., LTD. and NS PHARMA, INC. Plaintiff/Counter-Defendants.	REDACTED - PUBLIC VERSION

SAREPTA THERAPEUTICS, INC.'S RESPONSE TO NIPPON SHINYAKU CO. LTD. AND NS PHARMA, INC.'S OBJECTIONS TO SPECIAL MASTER ORDERS

Nippon Shinyaku Co. Ltd. and NS Pharma, Inc. (collectively, "NS")'s "Objections to Special Master Order #1" (D.I. 285)[1] seek a second bite at the apple in an effort to obtain overbroad, irrelevant discovery, and raise new issues and evidence that were not before the Special Master. Despite Special Master Squire's well-supported and well-reasoned opinions in Special Master Order Nos. 2 and 3 (D.I. 254, 263), NS frames his efforts as "fail[ure]s," "error," "erroneous," "ignor[ing]" legal standards, and "[f]lawed." (D.I. 285 at 1, 4-8.) To the contrary, the Special Master identified and then rigorously applied the proper legal standards to the facts of this case. It is NS's Objections, not the Special Master Orders, that distort both technical and legal principles in rehashing arguments considered and rejected by the Special Master. NS's renewed attempt to seek irrelevant sensitive business information from its main competitor should be rejected, and the Special Master's rulings should be adopted.

I. FACTUAL AND PROCEDURAL BACKGROUND

On March 11, 2022, NS served, inter alia, RFP Nos. 101 ("royalty rates paid in the field" for Duchenne muscular dystrophy (DMD) or any antisense oligonucleotide (AON) technology) and 149 (all documents related to a December 21, 2019 License, Collaboration, and Option Agreement between Sarepta and pharmaceutical company F. Hoffmann-La Roche Ltd. ("Roche Agreement") relating to ex-US rights to a variety of compounds). In its April 11, 2022 objections to NS's RFPs, Sarepta reasonably limited the scope of its agreed production for RFP No. 101 to the accused product, Vyondys 53®, and refused to produce an unredacted Roche Agreement, which had been published in redacted form as part of a Sarepta Form 10-K filing. Appx83-86.[2] Six

[1] While captioned as an objection to Special Master Order No. 1, it is clear upon reading that NS's objections are actually to Special Master Order Nos. 2 and 3. (*See* D.I. 285 at 1.)

[2] "Appx" cites refer to the combined Appendix created by NS's Appendix (D.I. 286) and additional key materials Sarepta submits herewith (starting at Appx303) to form one complete Appendix without re-submitting materials already on the docket.

months later, NS's counsel confirmed in letter correspondence that the scope of the dispute over license production was "[a]ll agreements/licenses ***related to developing exon-skipping oligonucleotides and/or Vyondys53®***[3] (including Sarepta's agreements with UWA, Biomarin, Roche and Royal Holloway), and any related consulting agreements (e.g., with the UWA inventors)." Appx328. Sarepta produced ***each*** of those enumerated agreements to NS. By April 4, 2023, the parties reached an impasse solely related to redactions to the Roche agreement. Appx93.

On May 15, 2023, counsel for NS indicated ***for the first time*** that they believed the impasse extended to a far broader scope of documents: "[l]icense agreements relating to DMD therapies beyond solely exon-skipping therapies (e.g., Sarepta's licenses for SRP-9001, including an unredacted version of the Roche Agreement)." Appx146.[4] Counsel for Sarepta explained there was no impasse, as this broadened scope had never been discussed. Appx145-146. NS eventually filed a Motion to Compel seeking a still yet broader scope of documents: "Sarepta's license agreement for [AON] and [DMD] therapies beyond merely the accused product Vyondys53®." (D.I. 247 at 1.) The parties submitted letter briefs on the dispute to the Special Master on June 15 and 19, 2023, and oral argument was heard before the Special Master on June 21, 2023. The Special Master issued his Order No. 2 on July 6, 2023, denying NS's Motion to Compel as "overbroad and not proportional to the needs of the case because it is not commensurate with the scope of the claims and defenses in the case and the parties' prior negotiations on this issue," but granting an *in camera* review of whether Sarepta's redactions to the Roche Agreement were appropriate. Appx5-7. After conducting the *in camera* review, the Special Master issued his Order No. 3 on July 14, 2023,

[3] All emphases added unless stated otherwise.

[4] The parties do not dispute that "SRP-9001," now marketed by Sarepta as Elevidys®, is a gene therapy treatment for DMD, and acts via a different mechanism of action than the exon-skipping therapies that are the accused products in this case.

ordering unredaction of a provision in the Roche Agreement deemed relevant to this case. Sarepta's other redactions in the SEC-filed version of the Roche Agreement were deemed "appropriate and properly encompass information that is not relevant to this case." Appx303-304.

II. THE SPECIAL MASTER'S RULINGS SHOULD BE ADOPTED

A. The Special Master Acknowledged and Correctly Applied the Rule 26 Standard

As NS concedes, the Special Master correctly set forth the standard for the scope of discovery under Fed. R. Civ. P. 26(b)(1) in Special Master Order No. 2. Appx3. Importantly, the Special Master also recognized that it is NS, the "party moving to compel," that "bears the burden of demonstrating the relevance of the requested information." *Id.* (quoting *Del. Display Grp. LLC v. Lenovo Grp. Ltd.*, No. 13-2018-RGA, 2016 WL 720977, at *2 (D. Del. Feb. 23, 2016)). Based on a fully-developed record, including oral argument, the Special Master properly applied the Rule 26 standard and determined that NS had not carried its burden.

NS suggests multiple times that the Special Master misunderstood the "claims and defenses" in the case, which set the boundaries for proper discovery under Rule 26. The record says otherwise. During oral argument, the Special Master confirmed that ***all*** asserted patents-in-suit and ***all*** accused products in the case were limited to "***exon-skipping*** treatments for DMD," specifically those that induce skipping of human exon 53. *See* Appx313-315, Hearing Tr. at 12:4-14:5. Indeed, this is a straightforward patent case relating to whether Sarepta's exon 53-skipping DMD therapy Vyondys 53® infringes the claims of NS's patents-in-suit (all of which are directed to antisense oligomers targeting exon 53), and whether NS's exon 53-skipping DMD therapy Viltepso® infringes the claims of UWA's patents-in-suit (all of which are directed to antisense oligomers targeting exon 53), with Sarepta as UWA's exclusive licensee. In view of this scope, the Special Master correctly determined that NS's demand then and now for "(1) ***all*** agreements

and licenses relating to ***all*** DMD therapies, regardless of whether they target exon 53 or are exon-skipping therapies, and (2) ***all*** of Sarepta's licenses relating to nucleic acid-based therapies known as AONs regardless of whether they skip exons or treat DMD" was "overbroad." Appx5.

The main crux of NS's argument is that it should be allowed essentially unfettered discovery into ***all*** of Sarepta's licenses so that its experts can assess the "comparability" of those licenses. (D.I. 285 at 5-6.) As NS concedes, however, that argument requires that there be a "colorable" claim of potential comparability (*id.* at 6), and the Special Master thoroughly and properly assessed that there was ***no*** such claim on this record. Delaware courts have consistently acted as gatekeepers, and have denied motions to compel license agreements when those agreements are irrelevant to the claims and defenses of the case. *See, e.g.*, *Robocast Inc. v. Microsoft Corp.*, No. 10-1055-RGA, 2014 WL 705288, at *2 (D. Del. Feb. 20, 2014) (denying motion to compel a purportedly "comparable" license when the license was deemed "not sufficiently related to the case at hand" (citation omitted)); *Medicis Pharm. Corp. v. Actavis Mid Atl. LLC*, 282 F.R.D. 395, 397 (D. Del. 2012) (holding as "substantially overbroad" requests seeking a "company-wide survey into products that are unrelated to even the field of use of the [accused] product."). The Special Master specifically questioned counsel regarding comparability at oral argument. *See* Appx313-319, Hearing Tr. at 12:17-13:8, 16:15-18:7 (Special Master questioning counsel about comparability issues). On the record that was made, the Special Master determined that he was "not persuaded that the broad scope of documents that Nippon Shinyaku seeks is relevant or that all such documents ***are even potentially comparable*** to the patents-in-suit." Appx6. NS is thus simply wrong that the Special Master "[f]ailed to apply the Rule 26 standard," "ignore[d] the relevancy standard," or ignored comparability. (D.I. 285 at 6.) The Special Master considered these issues, and correctly found that NS's motion was overbroad.

B. NS Misstates the Scope of the Parties' Prior Negotiations

NS is also wrong in stating that it "never so limited" the scope of its requests to "all agreements/licenses related to developing exon-skipping oligonucleotides and/or Vyondys53® (including Sarepta's agreements with UWA, Biomarin, Roche, and Royal Holloway), and any related consulting agreements (e.g., with the UWA inventors)." (D.I. 285 at 6.) Indeed, as the record before the Special Master indicated, this was the precise scope of production that NS proposed in October 31, 2022 letter correspondence, which Sarepta has included in its supplemental appendix. Appx328. The Special Master thus correctly observed it was "undisputed" that NS sent this correspondence (Appx6), and it was therefore not "error," as NS argues, for him to find that the scope of NS's motion exceeded the parties' prior negotiations. The quotes included in NS's Objections are from email correspondence that came more than six months later, after NS changed the scope of its request. The facts are clear: after the parties agreed on the scope of the dispute in October 2022, Sarepta eventually produced its "agreements with UWA, Biomarin, Roche, and Royal Holloway" to settle the dispute. NS subsequently expanded the scope of its request, leading to the dispute that was heard by the Special Master. The Special Master's decision that this expanded form of the dispute ran counter to the parties' prior discussions is supported by the record he considered.

C. The Special Master Correctly Assessed Proportionality

The 2015 amendments to the Federal Rules clarified that discovery must be "proportional to the needs of the case, considering the importance of the issues at stake in the action, the amount in controversy, the parties' relative access to relevant information, the parties' resources, the importance of the discovery in resolving the issues, and whether the burden or expense of the proposed discovery outweighs its likely benefit." Fed. R. Civ. P. 26(b)(1). This is a separate requirement beyond the baseline requirement of relevance. On the record before him, Special

Master Squire determined, with ample support, that NS's motion was "not proportional to the needs of this case." Appx5.

NS's Objections again contradict the record that it made before the Special Master. Despite telling the Special Master at oral argument that "we are not asking for all of Sarepta's licenses that it has," Appx311, Hearing Tr. at 10:21-23, its Objections confirm that it wants to do just that. (*See* D.I. 285 at 7 ("NS seeks to compel production of ***Sarepta's own*** licenses reflecting royalty rates paid in the field, including by Sarepta, for technology related to treatments for DMD or ASO technology…" (emphasis in original)). NS's oral argument reassurance is a distinction without a difference, since all of Sarepta's marketed drugs are "DMD or ASO technology." And just as NS tried to argue before the Special Master, NS's Objections again attempt to distort the facts relating to the scope of its own production. After NS's counsel stated on a May 22, 2023 meet and confer that NS had produced all of its own DMD-related licenses as purported justification for Sarepta doing the same, Sarepta's counsel noted that NS had not yet produced a publicly-referenced agreement relating to DMD therapies. Appx136-138. NS produced that agreement, then tried to argue before the Special Master that doing so proved the proportionality of their motion to compel. The Special Master shot that argument down, observing that the document was "seemingly irrelevant." Appx323, Hearing Tr. at 22:17-18. The proper, proportional scope of discovery is DMD-related licenses for exon 53 technology in the US market, and Sarepta produced those licenses to NS months ago. The scope is further confirmed by NS's own production; although its website touts development projects for DMD relating to skipping of exons 44, 45, 50, 51, and 55, NS has not produced a ***single*** agreement for any of those therapies (nor has Sarepta sought their production – because such discovery is not proportional to the needs of the case).

NS's allegation that the presence of a Protective Order removes all concerns relating to production of irrelevant, disproportionate sensitive business information does not provide Sarepta with any assurances. The requested discovery involves some of Sarepta's most commercially sensitive information, of the kind that the parties mutually agreed in their Protective Order could be redacted. The Special Master correctly found that these materials are not relevant or proportional to the needs of this case. And here any production of this extremely sensitive information creates huge risks of potential harm to Sarepta. The Federal Rules Committee's intent in adding an enhanced proportionality requirement to Rule 26(b)(1) was "to deal with the problem of overdiscovery" and "to encourage judges to be more aggressive in identifying and discouraging discovery overuse." *See* Fed. R. Civ. P. 26 advisory committee's note to 2015 amendment.

D. NS Cannot Raise New Arguments Regarding the Roche Agreement at the Objection Stage

NS improperly raises new arguments and positions for the first time in its Objections relating to the relevancy and redactions to the Roche Agreement. *See, e.g.*, *Net2Phone, Inc. v. eBay, Inc.*, No. 06-2469, 2008 WL 8183817, at *4 (D.N.J. June 26, 2008) ("[I]n an appeal of a Special Master's decision, the parties cannot raise entirely new arguments for the first time on an objection to a Special Master's Report." (citation and internal quotation marks omitted)). NS's Objections now seek to "unredact the pre-negotiated terms for the [redacted] and intellectual property relating thereto." (D.I. 285 at 10.) But, as reflected in Special Master Order No. 2, NS previously sought to compel Sarepta "to produce an ***unredacted version***" of the Roche Agreement in its entirety. Appx4. Counsel for NS confirmed during oral hearing that the dispute regarding the Roche Agreement "is whether or not we may have a ***completely unredacted*** version of that license." Appx310, Hearing Tr. at 9:13-16; *see also* Appx322, *id.* at 21:11-12 ("If the agreement's relevant, the ***entire*** agreement should be

produced."). Having sought overbroad relief from the Special Master and lost, NS is not permitted to now come back at the objections stage seeking more narrowly tailored relief that it could have sought in the first instance. The Court should uphold Special Master Order No. 3 on these grounds alone, which held that "all of the other redactions in the fully redacted version of the Roche Agreement are appropriate and properly encompass information that is not relevant to this case." Appx303-304, Order No. 3 at 1-2.

Regardless, the Roche Agreement is a broad collaboration agreement that involves ***different*** patents in ***different*** countries and many other products other than [redacted]. It is an agreement directed to ***ex-US rights.*** And contrary to NS's Objections, the Roche Agreement is ***not*** [redacted]; it is an option, [redacted]. *See* Appx359-360, [redacted] Dep. Tr. at 84:3-85:4. Accordingly, NS's insistence that it needs to see broad unredacted portions of this sensitive agreement because it purportedly relates to *Georgia-Pacific* factors 2 and 12 is mistaken. Factor 2 relates to "[t]he rates paid by the licensee..." and Factor 12 relates to "[t]he portion of the profit or of the selling price that may be customary…to allow for the use of the invention…" Since [redacted].

As further support, in another action in this district, Judge Andrews agreed that [redacted] of the Roche Agreement were ***not*** relevant to portions regarding gene therapy. *See* Appx373-374 (Sarepta Letter Br. at 3-4); Appx382, Hearing Tr. from *REGENXBIO Inc. v. Sarepta Therapeutics Inc.*, No. 20-1226-RGA (D. Del.) at 34:8-35:3. Judge Andrews ordered redaction [redacted] of the Roche agreement because "everyone agrees those dollars are just irrelevant" to gene therapy. *Id.*, *REGENXBIO* Hearing Tr. at 34:21-22. The inverse

is also true, and NS is not entitled to any unredaction of the Roche Agreement beyond that properly ordered in Special Master Order No. 3 specifically relating to [redacted].

E. Under NS's Own Definition, Nothing It Seeks Is Relevant

Finally, NS's Objections also misstate what is relevant for purposes of this case from a technical perspective, ***even under its own definition***. NS states in its Objections that "[l]icenses…which treat the same disease, by the ***same therapeutic goal*** and ***target the same population*** are relevant to assessing the market for the accused product, and should be available for the parties' experts." (D.I. 285 at 9.) By that definition, ***only*** licenses relating to exon 53-skipping therapies are relevant. Sarepta's unaccused exon-skipping therapies that are on the market or in development that target other exons do not "target the same population."[5] As for non-exon-skipping therapies for treatment of DMD, those have neither the "same therapeutic goal" nor "target the same population." For example, Sarepta's Elevidys® gene therapy product has a different mechanism of action and a different therapeutic goal than Sarepta's Vyondys 53® accused product. *Compare* the FDA Label for Elevidys®("expression of ELEVIDYS *microdystrophin* in skeletal muscle.") *with* Appx24, Vyondys 53® Label at 2 ("an increase in *dystrophin* production in skeletal muscle"). Nor are the amenable patient populations the same. *Compare* Appx36, Elevidys® Label at 1 *with* Appx28, Vyondys 53® Label at 6. In NS's own words, ***only*** Sarepta licenses relating to Vyondys 53®, its exon 53-skipping PMO product, are relevant and should be produced in this case. Sarepta has already done so for the licenses meeting that criteria that NS identified in its October 31, 2022 correspondence. Appx328 (October 31, 2022 letter correspondence); Appx316, Hearing Tr. at 15:1-8.

[5] The sole exception is a very small percentage of DMD patients with deletions involving exon 52 of the dystrophin gene, who can be treated with either exon 51 or exon 53-skipping products. Sarepta has produced [redacted].

III. CONCLUSION

For the above reasons, the Court should uphold Special Master Order Nos. 2 and 3.

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August 7, 2023

CERTIFICATE OF SERVICE

I hereby certify that on August 7, 2023, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF, which will send notification of such filing to all registered participants.

I further certify that I caused copies of the foregoing document to be served on August 7, 2023, upon the following in the manner indicated:

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